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09/818,228	03/27/2001	Kent L. Christopher	1246/39(a)	2216

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EXAMINER

PATEL, MITAL B

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 11/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/818,228

Applicant(s)

CHRISTOPHER, KENT L.

Examiner

Mital B. Patel

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment/Arguments

1. The amendment filed 9/17/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claims 1, 15, and 23, Applicant amended the claim to include the recitation "to supplement the patient's respiration through reduced work of breathing, improved alveolar ventilation, or washing out of carbon dioxide from the patient's airway". It appears that Applicant amended the above noted claims to include this recitation in order to overcome the Examiner's 35 U.S. 103 rejection in order to provide criticality for the specific flow rate recitation. However, the Application as originally filed does not provide the newly recited criticality as to why the particular flow rate is critical or important to the invention. As such, the amendment constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

2. In response to Applicant's arguments that Lethi teaches a device that restricts the patient's nasopharynx or oropharynx, it should be noted that Applicant's device also restricts the nasopharynx or oropharynx. The mere insertion of an element into an opening or orifice would restrict the opening or orifice in some manner. Therefore, the Examiner maintains that the Lethi device does not restrict the nasopharynx or oropharynx in so much as does the Applicant's device. Furthermore, the cuff of Lethi

does not have to be inflated and therefore would not restrict the nasopharynx or oropharynx.

3. In response to Applicant's remarks regarding "nothing in Lethi teaches or suggests a gas source with a flow rate of 4-40 liters per minute," it should be noted that the Examiner acknowledged in the previous office action that Lethi does not disclose the recited flow rate, and therefore, a 35 U.S.C. 103 rejection was set forth in which the Examiner stated that absent criticality, it would be obvious to one of ordinary skill in the art to provide the flow rate as set forth depending on the intended use, patient, and therapy.

4. In response to Applicant's remarks with respect to claims 3 and 16, there is no recitation in the claims that trimming of the device is required, and therefore, the Examiner maintains the prior rejection with respect to modifying the Lethi device as taught by Bowden.

5. In response to Applicant's remarks with respect to claims 5 and 18, the Examiner would like to point out that Lethi does teach a delivery tube **9** with two opposing end connectors **4a** and **5a**.

Claim Rejections - 35 USC § 112

6. Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. In claims 1, 15, and 23, Applicant amended the claim to include the recitation "to supplement the patient's respiration through reduced work of breathing, improved alveolar ventilation, or washing out of carbon dioxide from the patient's airway". It appears that Applicant amended the above noted claims to include this recitation in order to overcome the Examiner's 35 U.S. 103 rejection in order to provide criticality for the specific flow rate recitation. However, the Application as originally filed does not provide the newly recited criticality as to why the particular flow rate is critical or important to the invention. As such, the amendment constitutes new matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2, 6, 8, 11-15, 20, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi (US 6394093).

9. **As to claim 1**, Lethi teaches a nasopharyngeal catheter for open delivery of a continuous air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory

insufficiency, or sleep apnea syndrome, the nasopharyngeal catheter comprising a nasal catheter **1** having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without restricting the patient's spontaneous respiration; a delivery tube **9** adapted to extend below the patient's nostril connected to the proximal end of the nasal catheter; and a gas source. It should be noted that Lethi fails to specifically teach a flow rate of approximately 4 to 40 liters per minute. However, Applicant has not stated how the particular flow rate solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the flow rate would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a flow rate within the range of 4 to 40 liters per minute based on the intended use, intended patient, and intended therapy.

10. **As to claim 2**, Lethi teaches a nasopharyngeal catheter wherein the nasal catheter comprises a flexible plastic tube that can be cut to a desired length.

11. **As to claim 6**, Lethi teaches essentially all of the limitations except for a connector for removably attaching the proximal end of the nasal catheter to the delivery tube. However, it would be obvious to one of ordinary skill in the art to provide such a connector in Lethi so that if the pieces needed to be cleaned or replaced it would be easy to do so without having to discard the entire device.

12. **As to claim 8**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter has an inside diameter of up to approximately 3 mm. Applicant has

not stated how the particular dimension solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particular of the dimension would depend on the intended patient (infant, child, adult). Additionally, Lethi states that a "variety of airway tube diameters and lengths would be available for the differences in the physical dimensions of various patients. Therefore, it would be obvious to one of ordinary skill in the art to provide a particular dimension based on the intended patient.

13. **As to claim 11**, Lethi teaches essentially all of the limitations except for wherein gas is supplied through the nasal catheter at a back pressure of up to approximately 25 psi. However, Applicant has not stated how the particular back pressure solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the pressure would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a back pressure of 25 psi based on the intended use, intended patient, and intended therapy.

14. **As to claims 12**, Lethi teaches a nasopharyngeal catheter wherein the gas supplied through the nasal catheter comprises oxygen.

15. **As to claims 13**, Lethi teaches a nasopharyngeal catheter wherein the gas supplied through the nasal catheter comprises air.

16. **As to claim 14**, Lethi teaches essentially all of the limitations except for wherein the gas supplied through the nasal catheter comprises helium. However, Applicant has not stated how the particular gas supplied solves a stated problem or is advantages

over the prior art of record or provides unexpected results. Furthermore, the particulars of the gas supplied would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a specific gas such as helium based on the intended use, intended patient, and intended therapy.

17. **As to claim 15**, Lethi teaches a nasopharyngeal catheter comprising a nasal catheter **1** having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without restricting the patient's spontaneous respiration; the catheter being made of flexible material that can be trimmed to a desired length; a delivery tube **9** adapted to extend below the patient's nostril having a connector for attachment to the proximal end of the nasal catheter; and a gas source. It should be noted that Lethi fails to specifically teach a removable connector. However, it would be obvious to one of ordinary skill in the art to provide such a connector in Lethi so that if the pieces needed to be cleaned or replaced it would be easy to do so without having to discard the entire device. It should be noted that Lethi fails to specifically teach a flow rate of approximately 4 to 40 liters per minute. However, Applicant has not stated how the particular flow rate solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the flow rate would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a flow rate within the range of 4 to 40 liters per minute based on the intended use, intended patient, and intended therapy.

18. **As to claim 20**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter has an inside diameter of up to approximately 3 mm. Applicant has not stated how the particular dimension solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particular of the dimension would depend on the intended patient (infant, child, adult). Additionally, Lethi states that a "variety of airway tube diameters and lengths would be available for the differences in the physical dimensions of various patients. Therefore, it would be obvious to one of ordinary skill in the art to provide a particular dimension based on the intended patient.

19. **As to claim 23**, Lethi teaches a method for providing a supplemental continuous flow of air/oxygen to a spontaneously breathing patient, the method comprising advancing a nasopharyngeal catheter through a patient's nostril until the distal tip of the catheter is located in the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration. It should be noted that Lethi fails to specifically teach the step of supplying air/oxygen through the catheter at a flow rate of approximately 4 to 40 liters per minute. However, Applicant has not stated how the particular flow rate solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the flow rate would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a flow rate within the range of 4 to 40 liters per minute based on the intended use, intended patient, and intended therapy.

20. **As to claim 25**, Lethi teaches essentially all of the limitations except for the initial step of selecting the length of the catheter by advancing a catheter through a patient's nostril until the distal tip of the catheter is visible through the patient's mouth below the patient's uvula. However, it would be obvious to one of ordinary skill in the art to include this initial step since the length of the catheter will differ from individual to individual. Additionally, Lethi states that a "variety of airway tube diameters and lengths would be available for the differences in the physical dimensions of various patients. Therefore, it would be obvious to one of ordinary skill in the art to provide a particular dimension based on the intended patient.

21. **As to claim 28**, Lethi teaches essentially all of the limitations except for wherein the gas supplied through the nasal catheter comprises helium. However, Applicant has not stated how the particular gas supplied solves a stated problem or is advantages over the prior art of record or provides unexpected results. Furthermore, the particulars of the gas supplied would depend on the intended use, intended patient (infant, child, adult), and intended therapy. Therefore, it would be obvious to one of ordinary skill in the art to provide a specific gas such as helium based on the intended use, intended patient, and intended therapy.

22. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Bowden et al (US 6374827).

23. **As to claims 3 and 16**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter further comprises a plurality of markings indicating a series of common lengths for the nasal catheter. However, Bowden does teach a plurality of

markings for a variety of positions for different sized patients or children and for determining proper insertion. Therefore, it would be obvious to one of ordinary skill in the art to modify the catheter of Lethi to include a plurality of markings as taught by Bowden for a variety of positions for different sized patients or children and for determining proper insertion.

24. Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Brain (US 6055984).

25. **As to claims 4 and 17**, Lethi teaches essentially all of the limitations except for wherein the nasal catheter comprises a radio-opaque stripe. However, Brain does teach the use of a radio-opaque stripe to allow for easy identification of the location of a tube. Therefore, it would be obvious to one of ordinary skill to modify the catheter of Lethi to include a radio-opaque stripe as taught by Brain stripe to allow for easy identification of the location of the catheter.

26. Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Dali et al (US 3682171).

27. **As to claim 5**, Lethi teaches a nasopharyngeal catheter wherein the delivery tube further comprises two opposing ends with connectors for removable attachment to the gas source. Lethi fails to specifically teach a cap removably insertable into a connector that is not attached to the gas source. However, Dali et al. does teach a cap (plug) removably insertable into a connector that is not attached to the gas source. Therefore, it would be obvious to one of ordinary skill in the art to include of the cap of

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Dali et al. in Lethi's catheter to cap the connector when it is not in use to prevent it from collecting dust and bacteria in the connector and causing contamination.

28. **As to claim 18**, Lethi teaches a nasopharyngeal catheter wherein the delivery tube further comprises two opposing ends with connectors for removable attachment to the gas source. Lethi fails to specifically teach a cap removably insertable into a connector that is not attached to the gas source. However, Dali et al. does teach a cap (plug) removably insertable into a connector that is not attached to the gas source.

Therefore, it would be obvious to one of ordinary skill in the art to include of the cap of Dali et al. in Lethi's catheter to cap the connector when it is not in use to prevent it from collecting dust and bacteria in the connector and causing contamination.

29. Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Spofford et al (US 5297546).

30. **As to claim 7**, Lethi teaches a nasal catheter having essentially all of the claimed limitations except for the catheter comprising a hydrophilic coating. Spofford et al teaches a catheter comprising a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter. Therefore, it would be obvious to one of ordinary skill in the art to modify Lethi's catheter to have a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter.

31. **As to claim 19**, Lethi teaches a nasal catheter having essentially all of the claimed limitations except for the catheter comprising a hydrophilic coating. Spofford et

al teaches a catheter comprising a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter. Therefore, it would be obvious to one of ordinary skill in the art to modify Lethi's catheter to have a hydrophilic coating for limiting adhesion and subsequent build-up of mucous-type materials which would restrict the flow of oxygen through the catheter.

32. Claims 9, 10, 21, 22, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Daniell et al (US 6050260).

33. **As to claim 9**, Lethi teaches essentially all of the claimed limitations except for a humidifier controlling the humidity of the gas delivered through the nasal catheter. However, Daniell does teach a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient. Therefore, it would have been to one of ordinary skill in the art to modify Lethi's device to include a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

34. **As to claim 10**, the above combination teaches a nasopharyngeal catheter comprising a heater for controlling the temperature of the gas delivered through the catheter.

35. **As to claim 21**, Lethi teaches essentially all of the claimed limitations except for a humidifier controlling the humidity of the gas delivered through the nasal catheter. However, Daniell does teach a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

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Therefore, it would have been to one of ordinary skill in the art to modify Lethi's device to include a humidifier for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

36. **As to claim 22**, the above combination teaches a nasopharyngeal catheter comprising a heater for controlling the temperature of the gas delivered through the catheter.

37. **As to claim 26**, Lethi teaches essentially all of the limitations except for the method further comprising controlling the humidity of the air/oxygen supplied through the catheter. However, Daniell teaches the method of controlling the humidity of the gas delivered through the nasal catheter in order to prevent dehydration of the airways and nasal passages of the patient. Therefore, it would have been to one of ordinary skill in the art to include the method of Daniell for humidifying the gases delivered to the patient in order to prevent dehydration of the airways and nasal passages of the patient.

38. **As to claim 27**, the above combination teaches a method regulating the temperature of air/oxygen supplied through the catheter.

39. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lethi in view of Linder et al (US 3957055)

40. **As to claim 24**, Lethi teaches essentially all of the limitations except for cutting the proximal end of the catheter to a desired length so that the distal tip of the catheter will have a desired position relative to the patient's uvula and attaching the proximal end of the catheter to the connector on the delivery tube. However, Linder does teach the step of cutting a tube to the approximate length prior to use and then attaching the

connector on the tube. Therefore, it would be obvious to one of ordinary skill in the art to modify the method of Lethi to include cutting the tube so that a desired length is acquired prior to use.

Conclusion

41. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

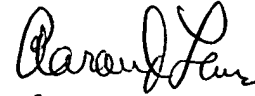
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Aaron J. Lewis
Primary Examiner

mbp